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# NOTICE OF ALLOWANCE AND FEE(S) DUE

1923 7590 01/30/2012 MCDERMOTT, WILL & EMERY LLP 600 13th Street, NW Washington, DC 20005-3096 EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/30/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,313	04/28/2008	Samuel S. Murray	38586-330002	4686

TITLE OF INVENTION: BONE MORPHOGENIC PROTEIN BINDING PEPTIDE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1740	\$300	\$0	\$2040	04/30/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 (571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) have its own certificate of mailing or transmission. 01/30/2012 Certificate of Mailing or Transmission MCDERMOTT, WILL & EMERY LLP I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. 600 13th Street, NW Washington, DC 20005-3096 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/587.313 04/28/2008 Samuel S. Murray 38586-330002 4686 TITLE OF INVENTION: BONE MORPHOGENIC PROTEIN BINDING PEPTIDE DATE DUE ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE APPLN, TYPE SMALL ENTITY NO \$1740 \$300 \$0 \$2040 04/30/2012 nonprovisional CLASS-SUBCLASS **EXAMINER** ART UNIT ROMEO, DAVID S 1647 530-326000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (B) RESIDENCE: (CITY and STATE OR COUNTRY) (A) NAME OF ASSIGNEE 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. ☐ Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_\_ (enclose an extra copy of this for Advance Order - # of Copies \_ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process)

an application. Confidentiality is governed by 37 C.F.R. 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/587,313	04/28/2008 Samuel S. Murray		38586-330002	4686	
MCDERMOTT, WILL & EMERY LLP 600 13th Street, NW Washington, DC 20005-3096			EXAMINER		
			ROMEO, DAVID S		
			ART UNIT	PAPER NUMBER	

DATE MAILED: 01/30/2012

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 94 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 94 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## **Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

	Application No.	Applicant(s)	
	10/587,313	MURRAY ET AL.	
Notice of Allowability	Examiner	Art Unit	
	DAVID ROMEO	1647	
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313 1. ☑ This communication is responsive to 12/30/2011.	(OR REMAINS) CLOSED or other appropriate comr GHTS. This application is	in this application. If not included nunication will be mailed in due course. <b>THIS</b>	€
<ol> <li>An election was made by the applicant in response to a rest</li> </ol>	riotion requirement set for	h during the interview on the restriction	
requirement and election have been incorporated into this action.	nction requirement set for	in during the interview on, the restriction	
3. X The allowed claim(s) is/are 1,3-5,11-13,22,23,25 and 38-43			
<ul> <li>4. ☐ Acknowledgment is made of a claim for foreign priority under a) ☐ All b) ☐ Some* c) ☐ None of the:</li> <li>1. ☐ Certified copies of the priority documents have</li> </ul>		r (f).	
<ol><li>Certified copies of the priority documents have</li></ol>	• •		
<ol><li>Copies of the certified copies of the priority do</li></ol>	cuments have been receiv	ed in this national stage application from the	
International Bureau (PCT Rule 17.2(a)).			
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		e a reply complying with the requirements	
<ol> <li>A SUBSTITUTE OATH OR DECLARATION must be submit INFORMAL PATENT APPLICATION (PTO-152) which give</li> </ol>			
6. CORRECTED DRAWINGS ( as "replacement sheets") must	t be submitted.		
(a) I including changes required by the Notice of Draftspers	-	ew ( PTO-948) attached	
1) hereto or 2) to Paper No./Mail Date			
<ul><li>(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date</li></ul>	s Amendment / Comment	or in the Office action of	
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t			
<ol> <li>DEPOSIT OF and/or INFORMATION about the deposit of B attached Examiner's comment regarding REQUIREMENT FC</li> </ol>			
Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date  4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. ☐ Interview Paper No 7. ☑ Examiner	nformal Patent Application Summary (PTO-413),  ./Mail Date s Amendment/Comment s Statement of Reasons for Allowance	
/David S Romeo/ Primary Examiner, Art Unit 1647			
i iiiiaiy Examinoi, Art Onit 1047			

#### **DETAILED ACTION**

# Response to Amendment

The declaration under 37 CFR 1.132 filed 12/30/2011 is sufficient to overcome the rejection of claims 1, 3, 4, 12, 13, 25 and 40 under 35 U.S.C. 102(b) as being anticipated by Kiefer (U. S. Patent No. 5,620,867) and the rejection of claims 1, 3, 4, 12, 13, 22, 25 and 38 – 40 under 35 U.S.C. 102(b) as being anticipated by Price (WO 96/21006).

## Election/Restrictions

This application is in condition for allowance except for the presence of claims 8-10, 14-21, 29, 32, 36, 37 and 44-49 directed to an invention non-elected without traverse. Accordingly, claims 8-10, 14-21, 29, 32, 36, 37 and 44-49 have been cancelled.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

## IN THE CLAIMS:

Cancel claims 8-10, 14-21, 29, 32, 36, 37 and 44-49.

The following is an examiner's statement of reasons for allowance:

Application/Control Number: 10/587,313 Page 3

Art Unit: 1647

The claims are directed to or encompass a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof, wherein said peptide or fragment increases the degree or rate of osteogenesis by BMP-2.

Kiefer (U. S. Patent No. 5,620,867) teaches a protein (Figure 3; paragraph bridging columns 8-9 through column 9, full paragraph 2) that comprises the amino acid sequence of SEQ ID NO: 1, as indicated in the sequence comparison below (Qy = SEQ ID NO: 1; Db = BMP):

Kiefer also teaches 19- and 16-kD fragments of the protein (Example 9).

According to the declaration filed 12/30/2011 (hereinafter, "Declaration"), the protein Kiefer discloses is also known as spp24 (Declaration, paragraph 5). spp24 inhibits bone formation (Declaration, paragraph 7). Fragments of spp24, with the exception of the claimed BPP (SEQ ID NO: 1), inhibit bone formation (Declaration, paragraphs 10 and 13). See also Sintuu (J Bone Joint Surg Am. 2011 Jun 1;93(11):1022-32), paragraph bridging pages 1026-1028 "Higher doses of TR-spp18...in combination with 10 μg/rhBMP-2 resulted in a significant decrease in bone-area formation as compared with the results obtained with the lower dose (0.1 mg) of TR-spp18 combined with 10 μg/rhbmp-2. ...compared with the positive control (10 μg/ of rhBMP-2 alone in Fig. 1), the low dose TR-spp18 resulted in a mild inhibitory effect on rhBMP-2 bone formation activity." Therefore, Kiefer does not teach a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof, wherein said peptide or fragment increases the degree or rate of osteogenesis by BMP-2.

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Art Unit: 1647

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, JEFFREY STUCKER, CAN BE REACHED AT (571)272-0911.

If submitting official correspondence by fax, Applicants are encouraged to submit official correspondence to the central fax number for official correspondence, which is (571) 273-0835.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/David S Romeo/ PRIMARY EXAMINER, ART UNIT 1647

DSR JANUARY 24, 2012